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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,311	04/19/2002	Toshio Miyata	2605/101	1616
2101	7590	09/08/2004	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			O HARA, EILEEN B	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 09/08/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,311

Applicant(s)

MIYATA, TOSHIO

Examiner

Eileen O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) 12-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,3,4,7-10 and 12-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1, 3, 4, 7-10 and 12-20 are pending in the instant application. Claims 1, 8, 9 and 10 have been amended and claims 2, 5-6 and 11 have been canceled as requested by Applicant in the Paper filed June 11, 2004.

Claims 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 3, 4 and 7-10 are currently under examination.

Withdrawn Objections and Rejections

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 26, line 23). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

4. Claim 10 remains objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. Although Applicant has amended the claim, the claim is improper because as written it depends from claims 1 and 9

Art Unit: 1646

and 3 or 4. For unacceptable multiple dependent claim wording, see MPEP § 608.01(n) *B. 3.*, for an example showing reference to two sets of claims to different features. See MPEP § 608.01(n) *A.* for examples showing acceptable multiple claim wording.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 3, 4 and 7-10 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, for reasons of record in the previous office action mailed Feb. 9, 2004, at pages 3-8, and below.

Applicant traverses the rejection, and disagrees with the Examiner's position that the utilities relating to the expression of MEG-3 in mesangial cells is irrelevant to the asserted utilities of the claimed invention, and asserts that it is the claimed invention that must be novel, and not its utility. Applicants' arguments have been fully considered but are not deemed persuasive. It is not a requirement for the claimed subject matter to have utility that can be met by no other product, process or technology. For example, a novel DNA ligase would be patentable, even though it has the same utility as that of other DNA ligases, that of ligating DNA for cloning purposes and which is essentially applicable to all of the members of that class of protein. However, the utility must be specific and substantial, and while the MEG-3 transcript in

kidney tissue may be specifically restricted to the mesangial cells, this does not confer a substantial utility to the nucleic acid or protein.

Applicant asserts that Applicant's opinion as to utility is typically sufficient to support utility, and the Examiner's opinion to the contrary is not sufficient basis for finding lack of utility, and cites MPEP § 2107.01. Applicants submits that Examiner has misinterpreted the cautions of MPEP § 2107.01 regarding lack of utility for inventions claiming a polynucleotide whose use is simply a "gene marker" or a "chromosome marker", which is a generic utility, and is not the same as claiming a specific gene marker for mesangial cells, which is sufficient for utility. Applicant further asserts that when an Applicant discloses a specific biological activity, [in the instant case, expression of MEG-3 in mesangial cells] and reasonably correlates that activity to a disease condition [proliferation of mesangial cells and accumulation of extracellular matrix in the pathology of glomerulosclerosis] then such assertions are "sufficient to define a specific utility for the invention".

Applicants' arguments have been fully considered but are not deemed persuasive. Although proliferation of mesangial cells is involved in the pathogenesis of glomerulosclerosis, any marker that could detect the mesangial cells could also be useful, such as the MEGSIN protein disclosed by the specification that is expressed specifically in the mesangial cells, and therefore, this is not a specific and substantial utility. Secondly, no evidence has been provided that correlates the expression of MEG-3 with any disease condition. The specification merely demonstrates that the claimed DNA is expressed in mesangial cells, as are many other genes. The nucleic acid could possibly have a specific and substantial utility as a marker for disease, if

Art Unit: 1646

for example, it was up or down-regulated in a disease or condition, but not such showing has been made.

Additionally, although the specification states on pages 28-29 that one of the characteristics in the human primary cell culture was that the Meg-3 gene is especially highly expressed in mesangial cells, it was also expressed at a fairly high level in human renal cortical epithelial cells. These levels are expressed in Table 1 as +++ (human mesangial cells) and ++ (human renal cortical epithelial cells), and these levels do not appear to be very different. Therefore, the Meg-3 gene also seems to be fairly highly expressed in renal cortical epithelial cells, and so it would not be a marker for mesangial cells alone. For these reasons and those discussed in the previous office action, the specification does not provide support for a specific and substantial utility for the claimed invention, and, the rejection under 35 USC § 101 is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3, 4 and 7- 10 also remain rejected under 35 U.S.C. 112, first paragraph, for reasons of record in the previous office action mailed Feb. 9, 2004, at page 8, and below.

Applicant traverses the rejection and asserts that the instantly claimed invention has a specific, substantial and well-established utility in identifying mesangial cells, detecting abnormalities in mesangial cells, studying the functions of mesangial cells and investigating causes of diseases related to mesangial cells. First, the specification has not disclosed any

Art Unit: 1646

method of detecting abnormalities in mesangial cells using the instant invention. As discussed above in the rejection under 35 USC § 101, use of Meg-3 to detect mesangial cells is not a specific and substantially utility, and use of a molecule to determine the role of that molecule is not a specific and substantial utility. Therefore, the rejection under 35 USC § 112 first paragraph is also maintained

It is believed that all pertinent arguments have been answered.

Conclusion

7. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.ispto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud